Stark Opening Statement At Hearing On Ensuring Kidney Patients Receive Safe And Appropriate Care

Monday, 25 June 2007

Opening remarks at today's hearing on safety concerns regarding the dosing of erythropoiesis stimulating agents (ESAs)

MEDIA ADVISORY, Thursday, June 26, 2007

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STARK OPENING STATEMENT AT A HEARING ON ENSURING KIDNEY PATIENTS RECEIVE SAFE AND APPROPRIATE ANEMIA MANAGEMENT CARE

WASHINGTON, D.C. -- Representative Pete Stark (CA-13), Chairman of the Ways and Means Health Subcommittee, delivered the following opening remarks at today's hearing on safety concerns regarding the dosing of erythropoiesis stimulating agents (ESAs), variations in utilization of ESAs across providers, and reimbursement issues.

"Delegate Christian-Christensen, Acting Administrator Norwalk, Dr. Jenkins, Mr. Vito, and the advocates and researchers on our third panel, thank you for appearing today before the Committee. Ms. Norwalk, I believe this is your last scheduled appearance before the Ways and Means Committee in your current position. I wish you luck in your future endeavors, and thank you for your service at CMS.

"As you know, the issue of Medicare's care for End Stage Renal Disease (ESRD) patients was one where our former Chairman Bill Thomas and I were in general agreement. We are here today to advance the discussion of safety issues and problems with the current reimbursement system that he started with his last hearing in December.

"In 2005, there were 321,000 Medicare beneficiaries receiving dialysis. Medicare spent $7.9 billion on their dialysis and drugs, including the anti-anemia drug Epogen. From 1991 to 2004, Medicare spending on Epogen for ESRD patients grew from $245 million to $2 billion - an increase of 716 percent.

"I fully recognize that Epogen, and other drugs like it, known collectively as "ESAs" (erythropoietin stimulating agents) are critical to treatment of anemia for these patients. No one disputes the underlying benefit of this therapy for people suffering from anemia. However, there are two major concerns regarding the use of ESAs.

"First, we must put patient safety first. We will hear from the FDA that when anti-anemia drugs are used to raise red blood cell levels above a certain threshold, there is a risk of death, blood clots, strokes, heart failure and heart attacks. We need to keep this in mind as we are dealing with populations that are more vulnerable to these conditions.

"Second, we are stewards of taxpayer dollars. The current Medicare reimbursement system creates incentives for higher dosing of ESAs, which lead not only to the aforementioned health risks but also come at a higher cost to taxpayers and beneficiaries. The OIG will present their new report, released today, documenting that large dialysis organizations make a profit on each dose of Epogen. And recent research published in JAMA shows that for-profit dialysis centers dose Epogen at higher levels than not-for-profit centers. The payment system leads to perverse incentives that we cannot ignore.

"I hear that Amgen is releasing some numbers today as part of an industry PR stunt. If Amgen and the rest of the industry are finally admitting there are health safety concerns and lowering Epogen dosing accordingly, I'm glad to hear it. This announcement proves, however, that there are additional efficiencies that can be gained by reducing Epogen doses. Clearly what I've been saying all along is true - the industry only responds when we threaten to do the right thing and remove their incentive to inflate doses as a way to reap profits.

"Medicare can be a better purchaser of care for dialysis beneficiaries, and can do so in a way that ensures more efficient use of ESAs and better health outcomes for beneficiaries.

"I would like to quote from a few letters I have recently received that set the stage for what we will be discussing today. Without objection, these letters will be entered into the Record.

"According to the National Institutes of Health, "between 1991 and 2005, the average weekly dose of EPO more than doubled." Furthermore, NIH data show that in 2005, "over half of [dialysis] patients had hemoglobin levels of 12.0 g/dl [grams per deciliter] or greater." Let's keep in mind that the FDA recommends hemoglobin levels not exceed 12.0, yet NIH data show that more than half of patients are at 12 or higher!

"The GAO writes, "Medicare could realize greater system efficiency if all ESRD drugs and services were bundled under a single payment system." And the Medicare Payment Advisory Commission writes, "a bundled rate would create incentives for providers to furnish services more efficiently...[and] would remove the financial incentive for facilities to overuse dialysis drugs...." Bundled payments would encourage more efficient use of ESAs. Please note that we must, without question, be sensitive to patient-specific variations in need for ESAs when structuring a bundled payment system. We are not recommending a one-size-fits-all system here. We can address those sensitivities with steps such as aggressive monitoring and quality programs.

"I am sorry that CMS is unable to deliver their long overdue report on ESRD bundling. This report was due more than two and a half years ago (October 1, 2005). At our hearing on this topic last December, CMS promised the report by summer of 2007. I understand CMS will give us some insight on that report today. I look forward to that testimony and receiving a commitment from CMS as to when precisely we will receive the report.

"Lastly, both Kaiser Permanente of Southern California and the Veterans Administration have written letters to discuss their practice patterns. Each is able to safely and effectively treat patients with doses up to 30 percent lower than what we see used in Medicare. The VA uses a one-third smaller dose of ESAs by administering the drug subcutaneously, rather than intravenously. Seventy-six percent of VA patients receive ESAs this way, with annual savings of between $2,987 to $4,095 per patient.

"Kaiser in Southern California also administers ESAs subcutaneously and confirms that doing so requires a dose up to 30 percent smaller than needed for intravenous use. Of even greater interest, Kaiser already uses bundled payments, and writes that "bundled payments are an effective way to pay dialysis centers and are consistent with both

positive health outcomes for beneficiaries and efficient use of Epogen."

"We must be certain that Medicare payments are structured to ensure the highest quality care to all beneficiaries. I am confident that we can do so for dialysis services in a more efficient manner that safeguards against the health risks of targeting higher red blood cell levels. This should be the Committee's goal for Medicare ESRD patients."

The National Institutes of Health letter on data presented in the 2006 Annual Data Report of the U.S. Renal Data System (USRDS) is available here.

The Government Accountability Office's testimony on a bundled payment system for ESRD services is available here.

The Medicare Payment Advisory Commission summary of research and recommendations on issues related to Medicare's payments for outpatient dialysis services is available here.

The Veterans Affairs letter on practice patterns in the treatment of anemia for ESRD is available here.

The Kaiser Permanente letter on bundled payments and subcutaneous use of EPO is available here.